

I. Introduction

ConAgra's internal documents demonstrate that the Sylvester, Georgia plant had ongoing problems that put ConAgra's peanut butter at risk for adulteration. ConAgra documents demonstrate ConAgra's utter disregard of its HACCP program regarding the time temperature requirements of its roaster to achieve a lethal kill of pathogens, ConAgra's poor general manufacturing practices, and ConAgra's knowledge and disregard of the health risks of producing peanut butter in its plant.

II. History of Bacterial Contamination at Sylvester plant

ConAgra's internal testing as far back as 2001 showed that its peanut butter contained high levels of bacteria. (Exhibit 1, pgs. 4-5). Its plant in Sylvester, Georgia was found in 2003 and 2004 to harbor *E.coli*. (Exhibits 4, 5 and 6).

Furthermore, in 2002, 2003, and 2004, the Sylvester plant had cockroach and "bug" infestations, "beetles" and issues with birds roosting and nesting. (Exhibit 2, pg. 1; Exhibit 3; Exhibit 5, pg. 2). The plant also had insanitation issues. (Exhibits 4, 5, 10 and 7).

III. October, 2004 Salmonella Adulteration

In October, 2004, ConAgra's peanut butter tested positive for *Salmonella*. (Exhibit 8, pgs. 1-2, 6; Exhibit 10, pgs. 1-3; Exhibit 13, pgs. 1-4). Testing showed that *Salmonella* was also present in the plant. (Exhibit 11). Yet the shift leaders reported that the operation had gone "smoothly" and typically on the dates in question. (Exhibit 9).

Due to the *Salmonella* findings, ConAgra destroyed more than 80,000 cases of peanut butter. (Exhibit 32, pg. 4).

IV. Sources of 2004 *Salmonella*, and Failures to Resolve These Issues

To address the 2004 *Salmonella* adulteration of its peanut butter, ConAgra's Safety Inspection and HACCP team made a number of recommendations that became ConAgra's "Sylvester Micro – Action Item List." (Exhibits 16, 17 and 18). Failure to address problems that ConAgra knew caused its peanut butter to be adulterated with *Salmonella* in 2004 led

to the adulteration discovered by the Centers for Disease Control in 2007. These areas are addressed separately below.

A. Failure to Replace the Faulty Roaster

In response to the 2004 *Salmonella* adulteration, ConAgra's HACCP team recommended that the roasting and rework kill processes be re-evaluated, "to insure that all products being roasted is pathogen free." (Exhibit 14, pg. 2). ConAgra's "Action Item List" dated November 4, 2004 added that ConAgra would "develop protocol and conduct micro testing required to validate kill step in roaster, confirm time & temperature required to achieve 9 log reduction of *Salmonella*." (Exhibit 16, pg. 2, 5). The Action Item List also stated that ConAgra would collect temperature profile data for the roaster, and determine the industry standard for roaster kill rates. (Exhibit 16, pg. 2-3). Finally, ConAgra was to complete a temperature distribution and heat penetration on the roaster. (Exhibit 16, pg. 5).

ConAgra's HACCP program identified the roaster as the critical control point (CCP) for eliminating biological hazards, and required the roaster to achieve temperature of 300 degrees, continuously, for a minimum of 5 minutes. (Exhibit 19, pg. 3).

ConAgra's temperature distribution study of its roaster in January, 2005, however, determined that temperature variations across the width of the roaster belt were as much as 100 degrees, and on average were 50 degrees. (Exhibit 20, pg. 2). The roaster was not meeting the CCP standard, yet ConAgra kept making peanut butter with it.

The electrical and structural problems with ConAgra's roaster are detailed in a February 8, 2005 internal evaluation. (Exhibit 21). Of further note was the fact that the roaster was designed to work as a dryer, operating up to 250 degrees – not at the 350 degrees at which it was currently being operated. (Exhibit 21, pg. 1). The failures of ConAgra's roaster were also documented in the March 11, 2005 audit of it conducted by Applied Technical Service, Inc. (Exhibit 22).

A report from ConAgra's Manager of Process Engineering, Richard Schumacher, arising from his March 17, 2005 roaster inspection, states that the roaster is, "old, in poor repair, dangerous from a food safety, personnel

and business point of view.” (Exhibit 23, pg. 4). His report concluded that the roaster needed to be replaced (Exhibit 23, pg.5).

A July, 2005 report states that the roaster presented a “Food Safety Hazard,” because, “low temperature locations in the roaster do not get adequate Micro kill.” (Exhibit 25, pg. 4). A July, 2005 presentation states that the current roaster puts ConAgra’s \$47 million of yearly profit from peanut butter at risk, including due to “undercooking for salmonella,” and that “replacing this roaster has been pushed off for seven years due to poor ROIC.” (Exhibit 26, pg.2). Memos from July, 2005 concluded that, “The roaster must be replaced in order for plant management to exercise effective control over the process.” (Exhibit 27, pg. 3; Exhibit 28, pg. 4). These concerns were repeated in later presentations. (Exhibits 29, 32, 33, 34, 35, 37, 38. Presentations linked ConAgra’s 2004 *Salmonella* adulteration to the roaster, “due to its insufficient heat sterilization of product.” (Exhibit 34, pg. 9). One of the risks identified as arising from ConAgra’s continued use of the faulty roaster was “Salmonella positive, no clear production cut-off.” (Exhibit 32, pg. 14).

Another issue raised in ConAgra’s March and July, 2005 reports was its use of the lowest grade of edible peanuts, resulting in higher “micro’s.” (Exhibit 23, pg. 2; Exhibit 27, pg. 1; Exhibit 28, pg. 3). ConAgra had used higher grade, lower contamination peanuts in the mid-90s but changed to the lower grade peanuts as a cost cutting measure. (Exhibit 27, pg. 1-2). This concern was echoed during later presentations, which “strongly recommended” that ConAgra re-evaluate its use of lower grade peanuts. (Exhibit 33, pg. 11-12).

In October 4, 2005, ConAgra stated that peanuts must be heated to 280 degrees for at least 18.1 minutes to kill *Salmonella*, but the Sylvester roaster could raise and hold peanuts to 280 for only about 5 minutes and has 100 degree variations from side to side. (Exhibit 32, pg. 12; Exhibit 33, pg.22).

On July 10, 2006 – nearly two years after it found *Salmonella* in its peanut butter caused by the ineffective heat sterilization of the roaster – ConAgra’s Corporate Division approved a plan to replace the roaster by April 2007. (Exhibit 44). Internal ConAgra emails evidence the frustration at the delay in replacing the roaster (“I feel this was one caught between processes. This roaster has been talked about for the entire year I have been

here at ConAgra.”; “don’t think we should hold this up for volume exercises ... and neither does Jim I don’t think, I believe he’d tell us we need to get this roaster into Sylvester and get it in there yesterday...”; “The roaster is a real issue in that it is more than past its useful life. ... In a true operating company spirit this CIR would have been submitted at least a year ago. It has been held in committee for more than a year and is a poster child for the issues with out capital approval process.” (Exhibit 39, pg. 1; Exhibit 40, pg. 1; Exhibit 42, pg. 1)).

Meanwhile, ConAgra continued to make peanut butter with the roaster that independent and internal experts labeled “dangerous.”

The Centers for Disease Control linked *Salmonella* to ConAgra’s peanut butter in February, 2007. The list of “FDA Suspect Date Codes,” also called the “focus lots,” included peanut butter manufactured from September, 2004 through December, 2006. (Exhibit 48). In all, 172 million pounds of peanut butter were recalled. (Exhibit 56, pg. 5).

ConAgra’s “Peanut Butter Recall Leadership Team” met on February 14, 2007 at 7:30am. Their discussion included, “Accelerate Roaster options.” (Exhibit 49).

In 2007, *Salmonella* was found on the top of the overhang at the discharge end of the roaster material, the vibratory conveyer feed blanching bucket conveyer, a vibratory leading to bucket conveyer at blanching bins, and “rejects from 3rd pass.” (Exhibit 51, pg. 3, 12, 34, 46). FDA environmental sampling found *Salmonella* tennessee from swabs collected on February 15 and 16, 2007, taken at the roaster drain at the peanut hopper gate surface and outer edge, and on equipment in the plant and in proximity to the peanut butter processing operation. (Exhibit 52).

As ConAgra told the FDA, of 10 positive environmental samples, 9 were from post-roasting. (Exhibit 56, pg. 8). ConAgra’s diagram presented to the FDA shows the clustering of environmental samples that tested positive for *Salmonella* just past the roasting step. (Exhibit 56, pg. 9).

Just as they did in 2004, ConAgra’s 2007 “Action Lists” include: verifying that the existing testing and sanitation procedures are the “right” ones and had been used, conducting a temperature distribution study for the roaster and to develop thermal process specifications for the roaster.

(Exhibit 53, pg. 2, Exhibit 54, pg. 2, 4). The Action List also included a review of raw peanuts for variation in aflotoxins, and using only medium peanuts short-term (Exhibit 54, pg. 4, 7).

B. Failure to Stop Moisture and Roof Leak Problems

In 2004, in response to the *Salmonella* adulteration of ConAgra's peanut butter, the ConAgra HACCP team made many recommendations related to moisture, leaking and condensation problems. (Exhibit 14). These recommendations were set forth in ConAgra's "Sylvester Action Item Lists," (Exhibits 16, 17 and 18).

The leaks and moisture issues at the Sylvester plant were, however, not resolved. For instance, in a May 13, 2005 memo regarding sanitation, ConAgra noted that some large areas on the second floor were wet mopped instead of cleaned with a floor scrubber because the second floor leaked down to the first floor. (Exhibit 24, pg. 4). The same memo notes that ConAgra had "spikes in coliform" during warm weather due to increased humidity. (Exhibit 24, pg. 3).

ConAgra attempted to fix its leaking roof, according to work orders, on July 11, July 18, and October, 29, 2005 and again on February 2, 2006. It also ordered repairs to stop water from getting inside the roaster. (Exhibit 31). The roof, however, was still never fixed, is evidenced by a November 16, 2006, internal ConAgra email stating, "We have leaks everywhere in the building." (Exhibit 45). Likewise, as noted in a December, 2006, email from an independent contractor noted the continued water leaks. (Exhibit 46, pg. 2).

The contractor's concerns are consistent with the testimony by sworn statement of Paul Hall about his inspections of the Sylvester plant and our personal observations there as well, as were described in our earlier report, including heavy brown stains running down multiple walls, water stains, East wall of the Unloading Area, heavy brown stains running down the walls in the Scalper/Destoner Room, water stains running down the walls in many areas of the Peanut Roasting Room, black mold at the roof/wall juncture along the East wall, and dark moisture stains on the overhead steel roof supports above the Line B filler and the Institutional filler.

In fact, internal ConAgra “brainstorming” notes dated 2/16/07 – two days after the recall -- list 6 locations of water leaks. (Exhibit 50, pg. 2).

ConAgra’s Action Plan in 2007 included, “replace roofing over production areas and extend roofing at receiving dock.” (Exhibit 53, pg. 3). Its List echoed the List from 2004, stating “identify roof leak locations” and corrective actions. (Exhibit 54, pg. 2).

In an April, 2007 power point presentation by ConAgra’s Vice President for Global Food Safety, ConAgra blamed the *Salmonella* adulteration, in part, on “roof leaks” and a faulty sprinkler head, which “introduced moisture into the environment.” (Exhibit 58).

C. Failure to Employ Proper Sanitation

The HACCP team made many recommendations in response to the *Salmonella* adulteration found in 2004 that were related to plant and employee insanitation. (Exhibit 14). These recommendations were included in the “Sylvester Action Item Lists.” (Exhibits 16, 17, 18, and 28). The sanitation issues, however, were never resolved.

The poor sanitation practices at the Sylvester plant are documented. For instance, the March, 2005, Applied Technology evaluation of the peanut roaster noted that large areas of the roaster were covered with oil and product residue. (Exhibit 22, pg. 2). A March 17, 2005, report found that open product zones above bins and conveyors created opportunities for contamination. (Exhibit 23, pg. 3). Peeling paint in several areas of the plant was also an issue. (Exhibit 23, pg. 3). The memo also mentioned concern about the dust levels and general cleaning issues due, in part, to the removal of the fines screen from the screeners. (Exhibit 23, pg. 3). ConAgra’s Engineer concluded, “There are many opportunities within the plant for improved sanitation and operations.” (Exhibit 23, pg. 5).

In the face of a *Salmonella* adulteration, and the HACCP’s team’s specific concerns regarding sanitation, ConAgra decided to cut back its sanitation force. In a May 13, 2005 memo, ConAgra specifically stated it wanted to, “improve or maintain sanitation performance using less labor hours.” (Exhibit 24, pg. 1). In the memo regarding this move, ConAgra noted that peanut debris builds up under the elevator bucket on the roaster, such that there is only a 1 inch clearance at the bottom of the bucket

conveyor and peanut debris comes into contact with the floor and the elevator buckets of the conveying system. (Exhibit 24, pg. 2).

A ConAgra memo dated July 12, 2005 found, “considerable build up of peanut dust both on the raw and post-roaster side of the operation” which increases opportunities for contamination. A particular concern was the buildup of peanut dust on the overhead structures directly over open post-roaster peanut storage bins. (Exhibit 27, pg. 3). In December 2006, the Georgia Department of Agriculture inspection noted there had been spillage on docks and around the roaster during its September 27, 2006 inspection. (Exhibit 47).

Brainstorming notes from 2007 about the *Salmonella* outbreak list the following sanitation problems: dust on overhead equipment, fixtures, ledges and conduit boxes, air vents that needed to be replaced, overhead blowback blowers exhaust thick with buildup, dirty changeover parts, the cap hopper needing cleaning, and the elevator and plastic cover needing sanitizing. (Exhibit 50).

The poor sanitation practices at the plant were confirmed in the sworn statement of Paul Hall and were evident in our inspection, where we observed grime, peanut residue build-up, grease, rust, stains, mold and peeling paint.

Again, ConAgra’s Action Lists from 2007 echo the Actions Lists from the 2004 *Salmonella* adulteration. The Lists include evaluating existing sanitation practices, provide more training for sanitation, and specialized training for sanitation of maintenance tools and equipment; build a new washroom for processed areas; ordering covers for the peanut storage bins, and evaluating raising bucket elevators. (Exhibit 53, pg. 1, 3; Exhibit 54, pg. 1, 4; Exhibit 55, pg. 1).

ConAgra’s statements to Congress in 2007, mention nothing about plant conditions and insanitation issues, and the role they played in this outbreak. However, the presentation to the FDA and Mr. Hall’s power point presentation on behalf of ConAgra from April, 2007, lists dust in the post roasting areas as contributing to the outbreak. (Exhibit 56, pg. 10, 13; Exhibit 38).

The fact that poor plant conditions, poor employee sanitation practices, and insanitation problems contributed to the *Salmonella* outbreak was confirmed by testing from February, 2007 at the plant, which found *Salmonella* on a broom from the upper blanching (Exhibit 51), the top and bottom of a wide sweeper broom from upper blanching, and a forklift located near the destoner. (Exhibit 51, pg. 33, 39).

D. Failure to Maintain Positive Air Flow

In response to the *Salmonella* adulteration discovered in 2004, ConAgra's HACCP team noted that the building should be under positive pressure from the filler/packaging/finished product area back toward the roaster, raw and outside areas of the plant. They instructed that the plant was to conduct an air balance study to identify what is needed to "provide clean positive air throughout the plant." (Exhibit 14, pg. 2). ConAgra's "Action Item List" from 2004 specifically required action on this issue, including conducting an air balance study and to "adjust air balance to ensure air flows from processed to raw receiving areas of plant. (Exhibit 16, pg. 1, 4). These items were included in the November, 2004 and February, 2005 Action Item Lists. (Exhibits 17, 18).

In March, 2005, ConAgra's Manager of Process Engineering notes that "the raw peanut area is at a higher pressure than the roaster/formulation/packaging area. The result is air flows from the raw area into other areas of the plant." (Exhibit 23, pg. 1). One of the concerns was that the pre and post roast air went to the same bag house and then was returned via ductwork to the raw side of the plant. He wrote, "This is improper from an air balancing, personnel safety and health and food safety point of view." (Exhibit 23, pg. 3).

ConAgra never resolved its air pressure issues. In its 2007 Action Item Lists, ConAgra lists, again, that it must address, "Air Separation" including "overall air balance," and "evaluate air systems." (Exhibit 53, pg. 3; Exhibit 55, pg. 1).

This issue was never mentioned to the FDA or to Congress by ConAgra as contributing to the *Salmonella* outbreak. However, Mr. Hall's power point specifically lists inadequate separation of pre roast/post roast processing areas and the fact that "during subsequent processing, handling

and filling, *Salmonella* found its way into the product" as causes of the outbreak. (Exhibit 58).

E. Failure to Control Vermin

ConAgra's 2004 HACCP team recommendations and Action Item Lists included many items related to bird, rodent and insect activity (Exhibits 14, 15, 16, 17, 18 and 28).

In his March, 2005 inspection Process Engineering Manager Richard Schumacher found that bees, birds and ants were "obvious on and around the sugar silo." (Exhibit 23, pg. 4).

Months after the *Salmonella* findings, on July 26, 2005, Joey Kimball, a ConAgra microbiologist, outlined recommendations for total exclusion of birds in and around the facility. (Exhibit 30). In addition to steps to prevent further bird roosting and nesting around the sugar tank and loading dock doors, his memo called for removal of all nesting material and droppings. ConAgra contracted with McCall Services for this work. (Exhibit 30).

A December, 2006, Georgia Department of Agriculture inspection found spider webs, and directed ConAgra to clean and monitor for spiders and insects. (Exhibit 47).

In our inspection of the plant, we observed several openings through which vermin could enter. We also observed evidence of vermin activity including dead cockroaches, live Sawtooth grain and Confused Flour beetles, flying moths, and rodent excreta pellets.

As it did in 2004, ConAgra's Action List arising from its investigation of the 2007 outbreak included addressing bird activity (Exhibit 54, pg. 2).

VI. ConAgra's Manipulation of the 2005 FDA inspection

In February, 2005, the F.D.A. inspected the plant because of anonymous complaints. (Exhibit 59). The complaints included allegations of insect infestation in the plant, poor sanitation, poor quality management, and, specifically, a bacterial contamination. (Exhibit 60, pg. 1).

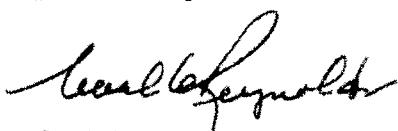
This was the first F.D.A. inspection of the plant since 2000. When the F.D.A. Investigator asked about the 2004 "micro hold" of product, ConAgra refused to provide any information about it. Eventually, instead of admitting the *Salmonella* adulteration, ConAgra informed the F.D.A. that the peanut butter in question was destroyed because it, "did not meet specifications." (Exhibit 59, pg. 7). ConAgra hid this important information from the F.D.A. Investigator, which impacted the Investigators' ability to thoroughly evaluate the complaints received about the Sylvester plant. To hide further its *Salmonella* adulteration issue, ConAgra provided testing results from October 6, 7, 12 and 13, 2004, showing only negative *Salmonella* tests, concealing the tests showing the adulteration. (Exhibit 59, pg. 7).

ConAgra's internal emails demonstrate its decision to hide this critical information from the F.D.A. A February 23, 2005 email reiterates that ConAgra will conceal its *Salmonella* adulteration from the F.D.A. and furthermore describes that, during the inspection, "We have adjusted tomorrow's AM schedule to not produce Crunchy when he is sampling to further reduce chance of positive." (Exhibit 61).

If ConAgra had been forthright with the F.D.A. during its inspection in 2005, the investigators would have more thoroughly inspected the plant and could have identified ConAgra's ongoing problems outlined above and made sure these issues were addressed.

VII. Conclusion

ConAgra disregarded the identified, known public health risks that caused the 2004 adulteration of its peanut butter with *Salmonella*. ConAgra failed to implement the measures needed to ensure the safety of its peanut butter that were recommended by ConAgra's HACCP team, and ConAgra's in-house and independent experts. ConAgra's disregard of these serious food safety issues led to the 2007-discovered *Salmonella* outbreak, which resulted in hundreds of food borne illnesses and the recall of millions of pounds of peanut butter.



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